

Message

From: Matthews, Keith [KMatthews@wileyrein.com]
Sent: 5/20/2019 4:38:16 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Nathan Rose [nathan.rose@oxitec.com]
CC: Reynolds, Alan [Reynolds.Alan@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: Materials for OX5034 application
Attachments: Oxitec_OX5034-OX513A Comparison_20 May 2019.pdf

Eric,

Many thanks for your helpful comments below.

Attached is the OX5034-OX513A letter revised as you suggested.

Please don't hesitate to call if you have any questions or if additional information would be of utility to BPPD.

Best,

Keith

Keith A. Matthews | Attorney at Law
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From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Monday, May 20, 2019 7:39 AM
To: Nathan Rose <nathan.rose@oxitec.com>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Matthews, Keith <KMatthews@wileyrein.com>
Subject: RE: Materials for OX5034 application

Hi Nathan,

I looked through the letter this morning. I think it generally looks good, I have two suggestions. One is to please add a line indicating it does not contain CBI. The second is to remove phone numbers and email addresses.

The docket will provide the public with the contact information for EPA if they need it and we will work through Oxitec/Wiley Rein as necessary and I have your contact information.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Nathan Rose [<mailto:nathan.rose@oxitec.com>]

Sent: Friday, May 17, 2019 8:56 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Keith Matthews <kmatthews@wileyrein.com>

Subject: RE: Materials for OX5034 application

Hi Eric

No problem to do so – we'll work on that basis.

Could you and the ETB team let us know whether the letter draft we sent yesterday contains sufficient information for your purposes? If so, we'll get the formal submission done asap.

Kind regards

Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: 16 May 2019 16:00

To: Nathan Rose <nathan.rose@oxitec.com>

Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Keith Matthews <kmatthews@wileyrein.com>

Subject: Re: Materials for OX5034 application

Nathan,

Please update the date to the day you submit all forms, don't use the earlier date. The only document that may require an updated MRID number might be the section G, the others are administrative documents and don't get MRID numbers. I can't remember if you submitted the section G as an MRID. If so then submit it as a new MRID.

Thanks.

Eric

Sent from my iPhone

On May 16, 2019, at 9:53 AM, Nathan Rose <nathan.rose@oxitec.com> wrote:

Hi Eric

Thanks for this – please see the attached document (in draft form, will be finalised for formal submission by Wiley Rein). If you could let us know what other information might be helpful, we'll make changes and then submit the document formally.

For the other documents – do these need a new MRID and should the dates on them be updated, or keep them the same as the original submission date of 11 March 2019?

Many thanks,

Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: 16 May 2019 15:39

To: Nathan Rose <nathan.rose@oxitec.com>

Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: Re: Materials for OX5034 application

Hi Nathan,

The documents you have listed below should be good for now.

Also no need to get an MRID for the summary document. We can look over it quickly before you formally submit it, since it doesn't have cbi you can just email a draft. Please copy Alan Reynolds and Mike Mendelsohn on the email.

I'll be out until Monday, but may get some time to look over it today or tomorrow.

Thanks.

Sent from my iPhone

On May 15, 2019, at 9:41 AM, Nathan Rose <nathan.rose@oxitec.com> wrote:

Hi Eric and Alan

Thanks again for a helpful call on Monday. I'm preparing the materials we discussed, and wanted to check a couple of things with you.

1) Changing identifiers of active and inert ingredients:

As requested, we'll update the identifiers to refer to tTAV-OX5034 (protein and genetic material) as the active ingredient, and DsRed2-OX5034 (protein and genetic material) as the inert ingredient. Can you let me know which documents in the administrative materials volume (MRID 50698700) you'd like us to update? I've already prepared the following:

- Basic CSF
- Label (Section B)
- Field trial protocol (Section G)
- Data matrix (both public and CBI versions)
- Application Form

If there are any others I should be updating too, please let me know.

Please also let me know if we should submit these using a new MRID number, and also whether the dates on each document should be updated to reflect the changes.

2) Summary document outlining differences between OX5034 and OX513A

We've drafted a summary document, and wanted to check whether it fulfils the requirements before we submit it – would it be helpful to send you a draft first? Also please advise whether this needs an MRID number.

Many thanks,

Nathan

Nathan Rose, D.Phil.

Head of Regulatory Science

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<Oxitec_OX513A-OX5034_comparison_DRAFT_16May2019.docx>

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